GE Healthcare

Pete McCabe
President and CEO
GE Healthcare, Surgery
384 Wright Brothers Drive
Salt Lake City, Utah 84116
U.S.A.
Pete.mccabe@ ge.com

Certified Mail Return Receipt Requested

IMPORTANT- ELECTRONIC PRODUCT RADIATION WARNING

PLEASE TAKE ACTION TO INFORM ALL USERS OF THE RELEVENT SYSTEM(S) OF THESE ISSUES AND HOW TO ADDRESS THEM

July 11, 2007

To: **Hospital Administrator**
Director/Manager of Radiology

Subject: **Product Compliance Issue**

Affected Products: **GEHC OEC 9900 ESP-15 Elite C-Arm**
GEHC OEC 9800 ESP-15 C-Arm

Our records indicate that your facility currently has one of the devices listed above. GE Healthcare has identified an issue affecting these devices

The details and symptom of the issue, as well as the associated solution is outlined below.

Air Kerma Rate Display Exceeds Allowable Error:

During internal testing GEHC Surgery has discovered that an issue in the displayed values of Air Kerma Rate such that cumulative air kerma could exceed the allowable 35% as specified in 21 CFR 1020.32(k)(6) under certain imaging conditions. Specifically, this error in the displayed value can exceed the allowable 35% when the system is operated at 15 pulses per second, in manual exposure rate control mode when extreme selections of high kVp values and low mA values are made in combination.

The accuracy of the displayed values of Air Kerma Rate and cumulative air kerma in all automatic exposure rate control modes and manual exposure rate control modes, both in continuous and pulsed operation is compliant otherwise. This issue does not impact the safety of operation of your system, however may result in non-compliance to 21CFR 1020.32 (k)(6).

Your GEHC Surgery field service representative will be contacting you to install a label to document this issue as well as provide your facility with an addendum to the operators' manual that also addresses this issue. A permanent software solution is currently under development and will be provided to your facility at no charge when the solution becomes available.

If you have any questions or concerns regarding these issues, please do not hesitate to contact the GEHC OEC service team for further information at 800-874-7378 option 8. Information is available at this number 24 hours per day, 7 days a week.

Thank you,

Pete McCabe
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